

55. (Withdrawn) The composition of claim 42, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

56. (Withdrawn) The composition of claim 42, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

57. (Original) The composition of claim 44, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

58. (Original) The composition of claim 44, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

59. (Withdrawn) The composition of claim 46, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

60. (Withdrawn) The composition of claim 46, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

61. (Withdrawn) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric human interferon-beta (β IFN- β) or biologically active mutein thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises glycine as a buffer, where said buffer is present at a concentration of

about 2 mM to about 5 mM, said composition having a pH of about 3.0 to about 4.0, and wherein
said formulation has an ionic-strength that is not greater than about ²⁰ ~~40~~ mM.

62. (Withdrawn) The composition of claim 61, wherein said ~~h~~IFN- β or biologically active mutein thereof is unglycosylated.

63. (Withdrawn) The composition of claim 62, wherein said mutein is hIFN- β _{ser17}.

64. (Withdrawn) The composition of claim 63, wherein said buffer is present at a concentration of about 5 mM, said pH is about 3.0, and said ionic-strength is not greater than about 20 mM.

65. (Withdrawn) The composition of claim 61, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

66. (Withdrawn) The composition of claim 61, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

67. (Withdrawn) The composition of claim 61, further comprising about 9% trehalose by weight per volume.

68. (Currently amended) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric human interferon-beta (~~IFN- β~~)(hIFN- β) or biologically active mutein thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 2 mM to about 5 mM, said composition having a pH of about

3.5 to about 4.5, and wherein said formulation has an ionic-strength that is not greater than about 4020 mM, said mutein having the ability to bind to IFN- β receptors.

69. (Currently amended) The composition of claim 68, wherein said rhIFN- β or biologically active mutein thereof is unglycosylated.

70. (Original) The composition of claim 69, wherein said mutein is hIFN- β_{ser17} .

71. (Original) The composition of claim 68, wherein said buffer is present at a concentration of about 5 mM, said pH is about 4.0, and said ionic-strength is not greater than about 20 mM.

72. (Original) The composition of claim 68, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

73. (Original) The composition of claim 68, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

74. (Original) The composition of claim 68, further comprising about 9% trehalose by weight per volume.

75. (Withdrawn) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric human interferon-beta (IFN- β) or biologically active mutein thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises sodium succinate as a buffer, where said buffer is present at a concentration of about 2 mM to about 5 mM, said composition having a pH of about 4.5 to

20

about 5.0, and wherein said formulation has an ionic-strength that is not greater than about 40 mM.

76. (Withdrawn) The composition of claim 75, wherein said ~~rh~~IFN- β or biologically active mutein thereof is unglycosylated.

77. (Withdrawn) The composition of claim 76, wherein said mutein is hIFN- β_{scr17} .

78. (Withdrawn) The composition of claim 75, wherein said buffer is present at a concentration of about 5 mM, said pH is about 5.0, and said ionic-strength is not greater than about 20 mM.

79. (Withdrawn) The composition of claim 75, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

80. (Withdrawn) The composition of claim 75, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

81. (Withdrawn) The composition of claim 75, further comprising about 9% trehalose by weight per volume.

82. (Currently amended) A method for increasing solubility of interferon-beta (IFN- β) or biologically active variant thereof in a pharmaceutical composition in the absence of human serum albumin, said method comprising preparing said composition with a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises a buffer in an amount sufficient to maintain the pH of said composition within plus or minus 0.5 units of a specified pH, where the specified pH is about 3.0 to about 5.0, said formulation having an ionic